

(6) Medical societies and other professional organizations; and

(7) Medicare carriers and fiscal intermediaries, health care prepayment plans and other affected agencies and organizations.

(f) If an exclusion sanction is effectuated because a decision was not made within 120 days after receipt of the QIO recommendation, notification is as follows—

(1) As soon as possible after the 120th day, the OIG will issue a notice to the practitioner or other person, in compliance with the requirements of paragraph (c) of this section, affirming the QIO recommendation based on the OIG's review of the case, and that the exclusion is effective 20 days from the date of the notice; and

(2) Notice of sanction is also provided as specified in paragraph (e) of this section.

[60 FR 63640, Dec. 12, 1995; 61 FR 1841, Jan. 24, 1996, as amended at 62 FR 23143, Apr. 29, 1997]

Subpart E—Effect and Duration of Exclusion

§ 1004.120 Effect of an exclusion on program payments and services.

The effect of an exclusion is set forth in § 1001.1901 of this chapter.

§ 1004.130 Reinstatement after exclusion.

(a) A practitioner or other person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with provisions of §§ 1001.3001 through 1001.3005 of this chapter.

(b) The OIG may also consider a practitioner's or other person's compliance with the certification obligation in § 1004.110(d) at the time of reinstatement.

Subpart F—Appeals

§ 1004.140 Appeal rights.

(a) *Right to preliminary hearing.* (1)(i) A practitioner or other person excluded from participation in Medicare and any State health care programs under section 1156 of the Act may request a pre-

liminary hearing if the location where services are rendered to over 50 percent of the practitioner's or other person's patients at the time of the exclusion notice is in a rural HPSA or in a county with a population of less than 70,000.

(ii) Unless the practitioner's or other person's practice meets the definition for psychiatric professional, vision care professional, dental professional, podiatric professional or pharmacy professional, the HPSA used by the OIG for determination of entitlement to a preliminary hearing will be the HPSA list for primary medical care professional.

(iii) Information on the population size of a county in order to determine entitlement to a preliminary hearing will be obtained by the OIG from the responsible officials of that county.

(2)(i) A request for a preliminary hearing must be made in writing and received by the Departmental Appeals Board (DAB) no later than the 15th day after the notice of exclusion is received by a practitioner or other person. The date of receipt of the notice of exclusion by the practitioner or other person is presumed to be 5 days after the date appearing on the notice, unless there is a reasonable showing to the contrary.

(ii) A request for a preliminary hearing will stay the effective date of the exclusion pending a decision of the ALJ at the preliminary hearing, and all the parties informed by the OIG of the exclusion will be notified of the stay.

(iii) A request for a preliminary hearing received after the 15-day period has expired will be treated as a request for a hearing before an ALJ in accordance with paragraph (b) of this section.

(iv) If the practitioner or other person exercises his, her or its right to a preliminary hearing, such a hearing must be held by the ALJ in accordance with paragraph (a)(3)(i) of this section unless the OIG waives it in accordance with paragraph (a)(6)(i) of this section.

(v) The ALJ cannot consolidate the preliminary hearing with a full hearing without the approval of all parties to the hearing.

(3)(i) The preliminary hearing will be conducted by an ALJ of the DAB in a city that the ALJ deems equitable to

all parties. The ALJ will conduct the preliminary hearing and render a decision no later than 45 days after receipt of the request for such a hearing by the DAB. Unless there is a reasonable showing to the contrary, date of receipt by the DAB is presumed to be 5 days after the date on the request for a preliminary hearing or, if undated, the date of receipt will be the date the DAB actually received the request. A reasonable extension to the 45-day period of up to 15 days may be requested by any party to the preliminary hearing and such a request may be granted upon concurrence by all parties to the preliminary hearing. Such request must be received no later than 15 days prior to the scheduled date of the preliminary hearing.

(ii) The only issue to be heard and decided on by the ALJ at the preliminary hearing, based on the preponderance of the evidence, is whether the practitioner's or other person's continued participation in the Medicare and State health care programs during the appeal of the exclusion before an ALJ would place program beneficiaries at serious risk. The ALJ's decision is to be based on the preponderance of the evidence.

(iii) In the interest of time, the ALJ may issue an oral decision to be followed by a written decision.

(iv) In those cases where the ALJ has stayed an exclusion after a preliminary hearing, a full hearing must be held and a decision rendered by the ALJ within 6 months. If, for any reason, the request for a full hearing before the ALJ is withdrawn or dismissed, the practitioner or other person will be excluded effective 5 days after the notice of the withdrawal or dismissal is received in the OIG headquarters.

(4) The preliminary hearing decision is not appealable or subject to further administrative or judicial review.

(5) A practitioner or other person found at the preliminary hearing not to place program beneficiaries at serious risk, but later determined to have been properly excluded from program participation after a full hearing before an ALJ, is not entitled to have the exclusion stayed further during an appeal to the DAB. Exclusions in such instances will be effective 5 days after re-

ceipt of the ALJ decision in the OIG headquarters.

(6)(i) After notice of a timely request for a preliminary hearing, the OIG may determine that the practitioner's or other person's continued program participation during the appeal before the ALJ will not place program beneficiaries at serious risk and waive the preliminary hearing. Under these circumstances, the exclusion will be stayed pending the decision of the ALJ after a full hearing. The hearing must be held, and a decision reached, within 6 months.

(ii) If the OIG decides to waive the preliminary hearing, the request for the preliminary hearing will be considered a request for a hearing before the ALJ in accordance with paragraph (b) of this section.

(b) *Right to administrative review.* (1) A practitioner or other person dissatisfied with an OIG determination, or an exclusion that results from a determination not being made within 120 days, is entitled to appeal such sanction in accordance with part 1005 of this chapter.

(2) Due to the 120-day statutory requirement specified in §1004.100(e), the following limitations apply—

(i) The period of time for submitting additional information will not be extended.

(ii) Any material received by the OIG after the 30-day period allowed will not be considered by the ALJ or the DAB.

(3) The OIG's determination continues in effect unless reversed by a hearing.

(c) *Rights to judicial review.* Any practitioner or other person dissatisfied with a final decision of the Secretary may file a civil action in accordance with the provisions of section 205(g) of the Act.

PART 1005—APPEALS OF EXCLUSIONS, CIVIL MONEY PENALTIES AND ASSESSMENTS

Sec.

- 1005.1 Definitions.
- 1005.2 Hearing before an administrative law judge.
- 1005.3 Rights of parties.
- 1005.4 Authority of the ALJ.
- 1005.5 Ex parte contacts.
- 1005.6 Prehearing conferences.